Prototype Development

Providing Effective Information to Consumers About Prescription Drug Risks and Benefits

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Prototype Development

- Goal - to develop a series of prototypes that exemplify different written approaches to conveying prescription drug information to consumers
  - Fictitious drug
  - Prototype development
  - Effectiveness information
  - Breakout sessions

Fictitious Drug Example: Rheutopia (arixalate)

- Previously used for practicing converting professional labeling to the “PLR” format
- Rheutopia’s labeling is fairly complex
  - Four indications: adult rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis
  - Associated with several serious risks (includes a boxed warning)
  - Meets the criteria for a Medication Guide
  - Administered by injection

Prototype Development Process

- Reviewed and considered:
  - Scientific literature
  - Comments and advice (from other meetings or submitted to FDA)
  - Current labeling practices and guidance
- Applied these findings/principles to the prototypes, concentrating on areas of agreement
- Developed four prototypes with different content and format

Content

- Core content in all prototypes, for example:
  - Uses
  - Side effects (serious and common)
  - What to do and what to avoid while taking the drug
  - How to take the drug
- Variable content in one or more, for example:
  - Pharmacological class
  - Ingredients
  - Date of leaflet
  - Standard statements

Format

- Ordering
- Headers
- Bulleting with short sentences/phrases
- “Chunking” similar concepts
- Type size
- White space/bolding
- Document length
- Reading level

Prototype 1

- Model: OTC “Drug Facts” labeling
  - Consumer-tested for OTC drug products
- Features
  - One page in length
  - Familiar format
  - Most concise

Prototype 2

- Model: “Highlights of Prescribing Information”
  - Consumer-friendly “Highlights” derived from the “Highlights” in the professional labeling (PLR format)
  - PLR format was physician-tested for prescription drug products
- Features
  - One page in length, but more detailed than Prototype 1
  - Boxed Warning
  - FDA approval date
  - Specific population information (i.e., not studied in children younger than 4)

Prototype 3

- Model: Built on the PLR format concept (two levels of information)
  - First level (summarized) information is explained in more detail in the second level
- Features
  - Two pages in length
  - Certain information is repeated
  - Question and answer format
  - Brief description of drug benefit beyond the uses, but does not contain numeric or visual presentations of effectiveness

Prototype 4

- Model: Medication Guide
  - Follows 21 CFR 208 requirements and Action Plan criteria/recommendations in the CMI guidance
- Features
  - Four pages in length
  - More detailed and comprehensive
  - Paragraph format
  - Contains standard statements

Presenting Benefit (Effectiveness) Information

- Challenges
  - How to summarize complex information
  - How to present quantitative efficacy information so that it will be understood and applied appropriately

Effectiveness Information: Rheutopia for Adult RA

- 4 randomized, DB, controlled trials
- Different inclusion/exclusion criteria
- Different control groups (placebo/active comparator) and doses
- Multiple measurements taken over time
  - ACR (scale measuring numbers of tender and swollen joints, global assessment (patient and physician), pain, etc.)
  - Physical function and disability (HAQ +/- SF-36 Health Survey)
  - Radiographic response (Total sharp score, Erosion score, Joint space narrowing score)
- Results reported
  - Percent of patients with improvement in RA using ACR criteria (i.e., ACR 20, ACR 50 and ACR 70) at 3, 6, and 12 months
  - Mean change in HAQ score at 6 months
  - Mean change in TSS, ES and JSN score at 6 and 12 months

Effectiveness Information

- What are the advantages and disadvantages of including effectiveness information?
- If effectiveness information is included, how should it be presented so that it is useful to consumers?
  - Feedback from this workshop
  - DDMAC study – "Experimental Study of Presentation of Quantitative Effectiveness Information to Consumers in Direct-to-Consumer (DTC) Television and Print Advertisements for Prescription Drugs" (74 FR 29490, June 22, 2009)
    - Drug efficacy (low versus high)
    - Type of visual format (none, pie chart, bar chart, pictograph)
    - Type of statistic (frequency, percentage, combination frequency and percentage, relative frequency, relative frequency and absolute rate, or none)

Breakout Sessions: Questions on Content and Format

1. Critique prototypes
2. Mix and match critical information
3. Presenting benefit (effectiveness) information
4. Communicating new information

Breakout Session: Process

- Breakout room assignment
- Remainder of morning and after lunch, each breakout room will discuss questions about content and format
- Reconvene in the afternoon for a summary of the breakout sessions